

# POSTSCRIPTS

Volume III Issue 12  
March 2013



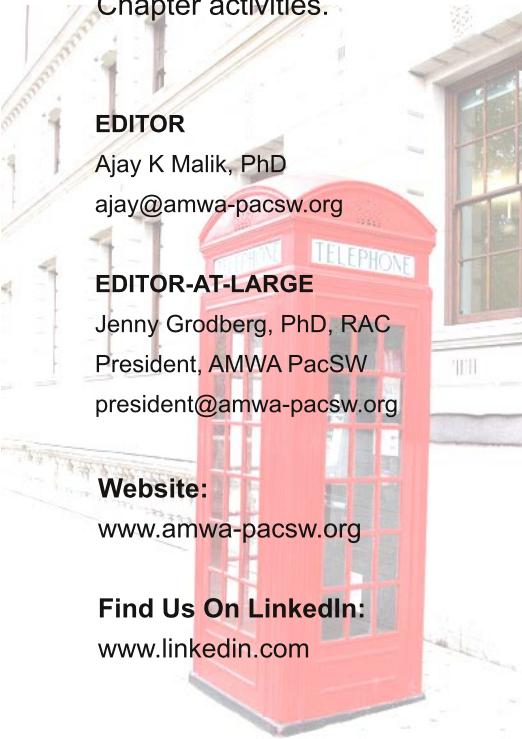
## POSTSCRIPTS

### AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

### MISSION STATEMENT

The mission of Postscripts is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, Postscripts publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of members, Postscripts includes news and event notices covering Chapter activities.



### SUBSCRIPTION

Postscripts is published monthly from February to December. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month. AMWA members can request past issues by sending an email to the editor.

### INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

### ADVERTISING

Postscripts is an advertisement-free publication. However, articles describing products and services relevant to medical writers may be considered or solicited. Contact editor.

**American Medical Writers Association  
Pacific Southwest Chapter**  
(AMWA Pac-SW)  
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# POSTSCRIPTS

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## IMPORTANT DATES

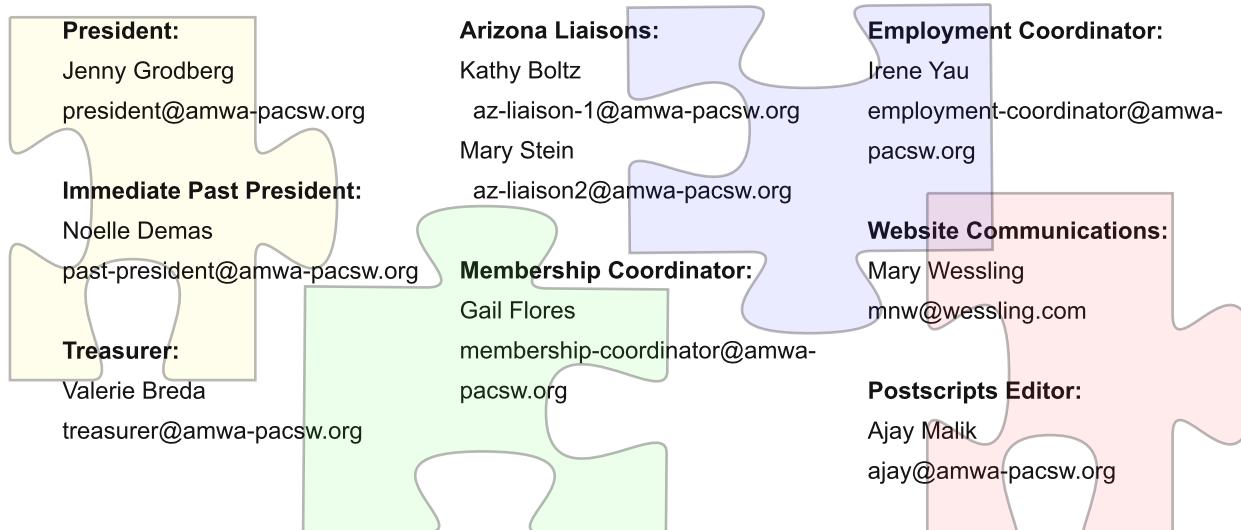
**March 6, 2013.** AMWA Northern California chapter sponsored webinar on Medical Writing Certification

**March 16, 2013.** AMWA Pac-SW Chapter's Annual Outreach Event at Amgen, Thousand Oaks

**April 28 – May 1, 2013.** AMWA Pacific Coast Conference

**November 6-9, 2013.** AMWA Annual Conference, Columbus, OH

## CHAPTER CONTACTS



## From the President's Desk

Greeting Friends and Colleagues,

WiseGeek.com defines "March Madness" as "the excitement of the final few weeks of the college basketball tournament....called March Madness simply because there are so many games going on throughout the country, usually during the same time". In other words, an energizing, fun race to an exciting finish.

Our race to the 2013 Asilomar conference kickoff (April 28-May 1) offers its own exhilarating March madness...yep, we Medical Writers "got game". Preparations are well underway for an educational and engaging experience and there's still time to register for one of 4 great workshops and informative open sessions. And it is with great pleasure I have the honor to announce the winner of our Inaugural Asilomar conference award, Michelle Merrigan. You'll be seeing her winning entry in the April issue of our Newsmagazine.

Speaking of our newsmagazine, let's count among our pre-Asilomar festivities engaging article by MaryAnn Foote and Jennifer Reichert, a terrific regulatory updates section "penned" by Sally Altman, Kelly Dolezal and Wim D'Haeze, our always informative and treasured de-MS-tifying Word and AMA-zing style articles (thank you Susan Chang and Dikran Torosser!), and a piece on Mentoring by Haripriya Shankar....a program we hope to institute in AMWA and something I'd love to see started at our Chapter level ...so perfect timing for starting this conversation!

And let's not forget a key kickoff event, our March 16 Outreach program brought to us through the generosity of our Amgen colleagues. You have until March 12 to register (contact Valerie Breda: treasurer@amwa-pacsw.org).

Who says medical writers don't know how to have fun...let the games begin!

Warmly,

Jenny

Jennifer Grodberg, PhD, RAC (US)  
President, AMWA Pacific Southwest Chapter

# Not the Sharpest Pencil in the Cup

By MaryAnn Foote

This article is the first in an occasional series highlighting an issue of concern to medical writers. Scenarios are based on the author's 20+ years of experience — personal and learning from others — in the biopharma industry, freelance world, and academia. Any scenario described has been altered to obscure the culprits and may, in fact, be a composite of several culprits.

**Client:** Mid-sized pharmaceutical company

**Conflict:** Selection of data for publication

**Introduction:** A Medical Director from the Professional Services organization of the company contacted a freelance medical writer for assistance in writing a series of papers based on the Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) for one of the company's products. The results of the 2 studies in the ISS and ISE were to be written as if all patients and all doses were in one large clinical trial. All papers would use on-label dosages and indications and were requested by the Marketing Department to fill gaps noted in a publication planning exercise.

**Issues:** While the preparation of a series of manuscripts based on a client's ISS and ISE is a routine and straight-forward request, the client in this scenario decided that not all doses would appear in the manuscripts. One dose in one study did not reach a significant p value and was to be omitted. The data — in the form of the ISS and ISE — had been submitted to the FDA and filed and also had been presented at several professional meetings. The trials were registered on Clinical Trials.gov and the reviewers and the Editor of the targeted journal did not appear to check the postings for drug dosages. The proposed first author was not the lead investigator in either of the clinical trials and the lead authors of the 2 previously published trials were not to be included as authors on the proposed manuscript, instead, 3 employees of the pharmaceutical company (Medical Director, another physician in Clinical, and a member of the Marketing Department) were to be listed as authors. The writer voiced concern about the "cherry-picking" of the data, exclusion of the lead authors from the 2 original studies, and the inclusion of authors who were not directly involved in the original clinical studies. (The

Sometimes, the negative data are more important and more telling than the positive data

company statistician who performed the integrated analysis was added to the Acknowledgement section.)

## Why do I nominate this scenario for Not the Sharpest Pencil in the Cup? Several reasons:

- Cherry-picking data – All doses in the ISS and ISE should have been reported in the integrated manuscript. Sometimes, the negative data are more important and more telling than the positive data. Physicians can prescribe any drug at any dose for any condition (even off label), and it would be important for a physician to know that one dose, while not harmful according to the limits of the clinical study, was not helpful to patients.

- Clinical Trial Registry – One purpose of the Clinical Trial Registry is to ensure that all patients in a study and all doses and dosages used are reported. The peer reviewers and Editor of the journal either failed to check the registry or did not understand the problems of omitting data.

- Choice of Authors – Authorship is an honor but it also has its responsibilities. While the lead author on the proposed manuscript appeared to be a competent physician, he was not involved in the planning and execution of the original studies or in the analysis of data from the original studies or the integrated study. The lead investigators of the original studies were not authors nor were they to be acknowledged in the proposed manuscript, although their work and their data were to be used. If these investigators were in a competitive academic setting, loss of a publication could have had untoward effects. The addition of company employees is a conundrum: They did identify a gap in marketing messages probably after a publication planning analysis and they "designed" an integrated analysis. Were

(continued on next page)

these activities enough to warrant authorship? The lead author, while engaged and eager, was not experienced and did not write any part of the manuscript. The statistician who was responsible for analyzing the data might have been considered as critical to the paper and included as an author.

The medical writer eventually asked to be removed from the project and not be acknowledged for writing assistance. What would you have done in this situation? The drug was approved and labeled doses were used, after all, but the selection of only doses with significant p values seemed somewhat unethical to the writer. Add in the authorship issues cited and the entire project might seem to not be the sharpest pencil in the cup.

**Acknowledgements:** Many thanks to Jim Yuen, Susan Siefert, and Linda Fossati Wood for review and comment on the first draft.

## AMWA Pac-SW Chapter's Annual Outreach Event March 16, 2013



Let's save the date! **Saturday March 16** marks the date when our chapter will welcome the academic community and other newcomers to come look us over at our annual outreach event. We are so fortunate that the prominent biopharmaceutical company Amgen will host the free event and provide complimentary lunch. Here is our chance to visit the Amgen campus in Thousand Oaks and meet with the movers and shakers from its many writing groups. The event, organized by Aaron Van Etton, promises to be a dynamic day packed with presentations by excellent speakers who will cover a broad range of topics; journal publications, regulatory writing, grants, freelancing, medical communications, and breaking into the career of medical writing. Also planned are several lunchtime roundtable discussions focusing on networking, how to develop a portfolio, and life-work balance.

Please stay tuned for more information. In early February, an announcement of the event, together with directions and a map will arrive in your e-mail box. Reservations will be required, so be sure to sign up early. This will be an exciting event not to be missed.

**Registration closes March 12.**

If interested, contact Valerie Breda ([treasurer@amwa-pacsw.org](mailto:treasurer@amwa-pacsw.org))

# Final Rule Issued on the Sunshine Act

By Jennifer Reichert, PhD

To enforce public disclosure of financial relationships between “applicable manufacturers” and “covered recipients” Section 6002 of the Patient Protection & Affordable Care Act was issued by the Centers for Medicare and Medicaid Services (CMS) on February 8, 2013. The Medicare, Medicaid, Children's Health Insurance Programs (CHIP); Transparency Reports and Reporting of Physician Ownership or Investment Interests can be viewed here:

[https://www.federalregister.gov/articles/2013/02/08/2013-02572/transparency-reports-and-reporting-of-physician-ownership-or-investment-interests-medicare-medicaid.](https://www.federalregister.gov/articles/2013/02/08/2013-02572/transparency-reports-and-reporting-of-physician-ownership-or-investment-interests-medicare-medicaid)

The final rule requires manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the CHIP to report annually certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable manufacturers are required to report certain physician ownership or investment interests. These data will be published by CMS on a public website. The final rule is effective on April 9, 2013. Manufacturers must collect the required information beginning on August 1, 2013 and report it by March 31, 2014.

The final rule applies to any drug, device, biologic, or medical supply, that is reimbursable by the federal government. The rule excludes over the counter drugs, but includes devices and medical supplies that, by law, require premarket approval by or notification to the U.S. Food and Drug Administration.

Covered recipients include physicians (MD, DO, DPM, OD, DCh) legally practicing in the US, but exclude residents and physicians employed by applicable manufacturer for work done specifically for that applicable manufacturer. However, physicians employed by agents of the applicable manufacturer are not exempt. Also included are teaching hospitals and group purchasing organizations that purchase, arrange for or negotiate the purchase of a covered drug, device, biological, or medical supply.

The following “nature of payment” categories were created:

- Consulting fees
- Compensation for other than consulting
- Honoraria

- Gift
- Entertainment
- Food & beverage
- Travel & lodging
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for faculty at accredited CME event
- Grant
- Space rental/facility fees

*]/ The category “other” which appeared in earlier drafts of the rule has been removed. Applicable manufacturers must find the category that best fits.*

Of interest to medical writers and others involved in publications was the guideline that payments for medical research writing and/or publication would be included in the research payment category, if the activity was included in the written agreement or research protocol and paid as a part of the research payment. The authors of the rule also stated that, “we believe that agreement to appear as an author of a ghostwritten article is an important relationship that should be reported, but believe there are sufficient existing nature of payment categories, such as compensation for services other than consulting, which can be used to describe the relationship.” Although “ghost writing” has long been disavowed by medical writers and manufacturers, regulators and the press continue to refer to it as if it is a common practice.

Finally, the rule lays out penalties of unintentional and intentional failure to submit required information in a timely manner. In the current regulatory and political environment, applicable manufacturers are likely to take a conservative approach to reporting transfers of value to physicians and institutions. On the other hand, many physicians and institutions are reluctant to be seen to be recipients of funding from manufacturers for fear of being perceived as being under the influence of funders. How will the press and politicians react to publication on the CMS website of transfers of value? That remains to be seen.

# What's Up(!) . . . at FDA and EMA

FDA updates By: **Sally Altman and Kelly Dolezal**

The FDA has disciplined two companies, Ben Venue Laboratories and Titan Medical Enterprises, for repeatedly failing to meet good manufacturing practice requirements, and another company, Globe All Wellness LLC, for distributing supplements with undisclosed ingredients. These are part of the FDA's continued efforts to counter falsified and substandard drugs, a subject on which the FDA released a report this month. Several new drugs for the treatment of diabetes mellitus and a new treatment for myeloma are among products that met the regulatory standards for approval. The FDA is allowing controlled importation of Lipodox, a cancer drug that is unapproved in the US, until distribution of Doxil, a newly approved generic, alleviates the shortage of the compound doxorubicin hydrochloride.

## Selected FDA Announcements<sup>1</sup>

01/31/13 Ben Venue Laboratories in Bedford, Ohio was issued a permanent consent decree after repeatedly failing to meet good manufacturing practice requirements or promptly address issues found during inspection, including debris from deteriorating equipment in injectable drug products. Ben Venue is a Boehringer Ingelheim Company.<sup>1</sup>

02/04/13 To help alleviate the shortage of the cancer drug doxorubicin hydrochloride liposome injection, the FDA approved the first generic cancer drug, Doxil. The FDA will also continue to allow controlled importation of Lipodox, which is not approved in the United States, until enough Doxil supplies are produced to meet demands.<sup>1</sup>

02/07/13 The FDA has issued a guidance document titled "Guidance for Industry, Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease" to help researchers better select patients with early Alzheimer's disease for clinical trials<sup>1</sup>

02/08/12 Titan Medical Enterprises has been ordered to halt manufacture and distribution of drugs and dietary supplements after repeatedly failing to meet good manufacturing practice requirements.<sup>1</sup>

02/13/13 The FDA released a report titled "Countering the Problem of Falsified and Substandard Drugs" to address the importance of being fully prepared to meet drug safety standards in a global market.<sup>1</sup>

02/14/13 US Marshalls seized dietary supplements that contain undisclosed sibutramine hydrochloride, an active ingredient in the withdrawn obesity drug Meridia, from Globe All Wellness, LLC. in Hollywood, Florida.<sup>1</sup>

## Selected FDA Approvals<sup>2</sup>

Drug	Indication	Company
Nesina	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>2</sup>	Takeda Pharms USA
Oseni	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>2</sup>	Takeda Pharms USA
Kazano	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>2</sup>	Takeda Pharms USA
Suclear; PEG-3350	Cleansing of the colon in preparation for colonoscopy in adults. <sup>2</sup>	Braintree Labs
Kynamro	An adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). <sup>2</sup>	Genzyme Corp
Ravicti	Chronic management of adult and pediatric patients ≥2 years of age with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. <sup>2</sup>	Hyperion Therapeutics
Pomalyst	For patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. <sup>2</sup>	Celgene

For additional information, including full listings of biologic license application approvals, abbreviated new drug application approvals, applications for generic drugs and supplements to new drug applications or biologic license applications, see:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports ReportsMenu>

1. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/>

2. <http://www.fda.gov/NewsEvents/ProductsApprovals/default.htm>

# What's Up(!) . . . at FDA and EMA

EMA Updates By: **Wim D'Haeze**

## EUROPEAN MEDICINES AGENCY (EMA) ALERTS (18 JAN 2013 THROUGH 20 FEB 2013)

The alerts listed below cover the period from January 18, 2013 through February 20, 2013. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to [What's New](#) on the EMA website.

### GUIDELINES

- Draft guideline on biosimilars containing low-molecular-weight heparins (open for publication consultation)<sup>a</sup>
- Guideline on non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins (open for publication consultation)<sup>b</sup>

### REPORTS/PAPERS

- Reflection paper on good-clinical-practice compliance in relation to trial files (paper and/or electronic) for management, audit, and inspection of clinical trials (open for public consultation)<sup>c</sup>

### APPROVALS/REFUSALS

Compound	Indication/Use	Applicant	Advice [Note]
Maruxa <sup>d</sup>	Patients with moderate to severe Alzheimer disease	Krka, d.d., Novo mesto	Positive opinion
Actelsar HCT <sup>e</sup>	Hypertension	Actavis Group hf	Positive opinion
Jetrea <sup>f</sup>	Adults with vitreomacular traction	ThromboGenics NV (Belgium)	Positive opinion
Tolucombi <sup>g</sup>	Hypertension	Krka, d.d., Novo mesto	Positive opinion
Raxone <sup>h</sup>	Leber's hereditary optic neuropathy (LHON)	Santhera Pharmaceuticals GmbH (Germany)	Negative opinion

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

### GENERAL ANNOUNCEMENTS

- The PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) project reaches milestone.<sup>i</sup>
- European Medicines Agency pre-authorisation procedural advice for users of the centralized procedure; integrated version compiled for printing purposes.<sup>j</sup>

(continued on next page)

## ... EMA Updates

### LINKS:

- a. [\[Link\]](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500138309)
- b. [\[Link\]](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500138309)
- c. [\[Link\]](http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500138893&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc)
- d. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002658/smops/Positive/human_smop_000472.jsp&mid=WC0b01ac058001d127)
- e. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002676/smops/Positive/human_smop_000468.jsp&mid=WC0b01ac058001d127)
- f. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002381/smops/Positive/human_smop_000466.jsp&mid=WC0b01ac058001d127)
- g. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002549/smops/Positive/human_smop_000465.jsp&mid=WC0b01ac058001d127)
- h. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002425/smops/Negative/human_smop_000470.jsp&mid=WC0b01ac058001d127)
- i. [\[Link\]](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/02/news_detail_001713.jsp&mid=W0b01ac058004d5c1)
- j. [\[Link\]](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004069)



**EXPANDING OUR HORIZONS**

**November 6-9, 2013  
Columbus, OH**

**AMWA's 73rd Annual Conference**

<http://www.amwa.org/default.asp?id=575>

# HAWAII — Kaua'i Oceanfront Resort

**Islander on the Beach, Kapaa, Kaua'i, is a beachfront resort set on 6 beautiful tropical acres with breathtaking views of the blue Pacific Ocean.**

Islander on the Beach, Kapaa, Kaua'i, is a beachfront resort set on 6 beautiful tropical acres with breathtaking views of the blue Pacific Ocean.

Located 7 miles north of Lihue Airport, Islander on the Beach is an old Hawaii resort, with pool, jet spa, gas barbeques, and Tiki bar. Walk to dozens of shops and restaurants, as well as ancient heiau and Queen's bath. During whale season, see whales from beach and from lanai of Unit 361.

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- Free Hawaiian coffee
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- Activity drawers with games and beach toys
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- Kitchenette with bar refrigerator, microwave, toaster, blender, and coffee pot
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**IOB361@yahoo.com**  
 State of Hawaii License  
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### Unit 111

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  - garden view
- raised lanai for security
- VRBO listing 430323

### Unit 361

- third floor, sleeps 2
  - king bed
- spectacular ocean view
- fall asleep listening to the waves
- VRBO listing 424621

VRBO is Vacation Rentals by Owners at [www.vrbo.com](http://www.vrbo.com)

# de-MS-tifying Word

By Susan Chang

Reprinted from: Postscripts. 2012 Aug;2(6):3.

Below I've listed some of my favorite keyboard shortcuts for special characters/formatting and a great trick using the AutoCorrect function. Get your work done faster and enjoy what remains of the summer!

**NOTE:** Keys separated by a plus sign (+) = press the keys simultaneously.

Keys separated by a comma (,) = press the first key(s) followed by the next key(s).

## Fast & Furious Formatting

To insert this...	...press this.
Nonbreaking Space	<b>CTRL+ SHIFT + SPACE.</b> Use this to avoid a misplaced line break, such as a break between a number and its units (not preferred in most style guides).
Nonbreaking Hyphen	<b>CTRL+ SHIFT + [-].</b> Use this to avoid a line break at the hyphen in a hyphenated word (not preferred in most style guides).
Subscript Font	<b>CTRL+ [+], word.</b> You can also use this to toggle back to regular text.
Superscript Font	<b>CTRL+ SHIFT + [+], word.</b> You can also use this to toggle back to regular text.

## Go Global

Even if you don't write for countries outside the US, you will likely need international characters. This is especially common for authors in a reference list.

**NOTE:** To type a lowercase character when using a key combination that includes the SHIFT key, hold down the **CTRL+ SHIFT+ (symbol)** keys simultaneously, then release before you type the letter.

To insert this...	...press this.	To insert this...	...press this.
à, è, ì, ò, ù, À, È, Ì, Ò, Ù	<b>CTRL+ `</b> (ACCENT GRAVE), letter	ã, ñ, õ, Ã, Ñ, Õ	<b>CTRL+ SHIFT+ ~</b> (TILDE), letter
á, é, í, ó, ú, ý, Á, É, Í, Ó, Ú, Ý	<b>CTRL+ '</b> (APOSTROPHE), letter	ä, ö, ü, ÿ, Ä, Ö, Ü, ÿ	<b>CTRL+ SHIFT+ :</b> (COLON), letter
â, ê, î, ô, û, Â, Ê, Î, Ô, Û	<b>CTRL+ SHIFT+ ^</b> (CARET), letter	å, Å ç, Ç	<b>CTRL+ SHIFT+ @</b> , a or A <b>CTRL+,</b> (COMMA), c or C

## AutoCrafty

Go to File tab → Word Options → Proofing → AutoCorrect Options → AutoCorrect tab.

Enter a shortcut to replace terms that you use often in the "Replace/With" boxes. Be sure that the "shortcut" text you enter is not another word or abbreviation!

Replace:	With:
shortcut	term that you dislike typing
ltag	Long-term Analysis Group
mactd	Musculoskeletal and Connective Tissue Disorders
maintenence	maintenance
ugkg	µg/kg

As you can see, some commonly misspelled words are already entered here. You can add your own as well. I ALWAYS type "template" instead of "template." ALWAYS. So I have the option of entering it here instead of improving my typing skills.

**TIP:** Copy/paste from your document to the "Replace/With" box for symbols such as "µ." Be thoughtful with this trick. Replacing "ug" with "µg" would be a disaster! µgggg! But replacing "mcg" with "µg" would work, even on the text you copy/paste into your document from the discovery scientist!

Special thanks to Rebecca Anderson for her contribution on international characters!



# AMA-zing Style — the AMA Manual of Style Column

By Dikran Torosser, PhD, Amgen Inc.

## A primer on DNA and amino acids

Many medical writers work on publications detailing basic research. These publications often include various manipulations of DNA and proteins. The AMA manual of style covers some useful science behind these molecules.

**DNA.** The determination of the structure of DNA represented a pivotal historical event for humanity. Recent cutting-edge research into DNA structure highlights its continuing importance, eg, see the remarkable recent information from Gentile *et al* (2012); <http://pubs.acs.org/doi/abs/10.1021/nl3039162><sup>1</sup>. In brief, the AMA manual of style contains a section on DNA and protein related nomenclature.

The nucleic acids DNA and RNA are nucleotide polymers. Deoxyribonucleic acid, or DNA is the genetic code contained in chromosomes. It is composed of *bases* (*pyrimidines and purines*), a sugar (deoxyribose), and phosphate groups. Structurally, it is a helical polymer of deoxyribose linked by phosphate groups; 1 of 4 bases project from each sugar molecule of the sugar-phosphate chain. A base-sugar unit is a nucleoside. A base-sugar-phosphate unit is a nucleotide. The manual has schematic pictures.

A *codon* is a sequence in a DNA molecule that (ultimately) codes for an amino acid, or signal (eg, start

transcription, stop transcription). Codons, are also referred to as *codon triplets* eg, CAT ATC ATT. *Promoters* are DNA sequences that promote transcription of DNA into RNA (ribonucleic acid). The phosphates that join the DNA nucleotides link the 3'-carbon of one deoxyribose to the 5'-carbon of the next deoxyribose (see the AMA manual for an excellent explanation of this numbering). When representing long sections of DNA in a publication, spaces every 5 or 10 bases are customary visual aids: eg, GAATT CCTGA.

**Sequence variations.** Many publications detail man-made mutations in DNA. Usually, these medical publications use abbreviations to denote these mutations. As usual, textual explanations should accompany the shorthand terms at first mention.

**Amino acids.** Twenty amino acids are ultimate products of the genetic code. Each has one or more distinct codons in DNA, eg, GCU, GCC, GCA, and GCG code for the simple amino acid alanine. Although amino acids have systematic names (eg, alanine is 2-aminopropanoic acid), trivial names are the most widely used. The side chains of amino acids are known as *R groups*.

The carboxyl (COOH) group is referred as the  $\alpha$ -carboxyl group. The amino ( $\text{NH}_2$ ) group is referred to as the  $\alpha$ -amino group. (Amino acids are not really neutral, but rather contain  $\text{NH}_3^+$  and  $\text{COO}^-$ ; that is why they dissolve in water, a polar solvent). Peptide bonds between the  $\alpha$ -carboxyl group of one amino acid and the  $\alpha$ -amino group of the next function to make up a peptide. By convention, the amino end of the peptide is represented on the right. The symbols  $\text{NH}_2$  and COOH may be included in the representation of the sequence, as follows:  $\text{NH}_2\text{-Gly-Ile-Val-Glu-Ala-Ser-Tyr-COOH}$

Further details can be found on pages 584-608 of the AMA Manual of Style 10th edition.

## REFERENCE

1. Gentile F, Moretti M, Limongi T, Falqui A, Bertoni G, Scarpellini A, Santoriello S, Maragliano L, Proietti Zaccaria R, di Fabrizio E. Direct imaging of DNA fibers: The visage of double helix. *Nano Lett.* 2012;12:6453-6458

Abbreviation	Base	Nucleoside; Nucleotide Residue in DNA	Molecular class
A	adenine	deoxyadenosine	purine
C	cytosine	deoxycytidine	pyrimidine
G	guanine	deoxyguanosine	purine
T	thymine	deoxythymidine	pyrimidine

A 1-letter designation (A, C, G, T) represent bases. When a base is described that cannot be firmly identified as A, C, G, or T, other single-letter designators reflecting biochemical properties may be used

Abbreviation	Base	Nucleoside; Nucleotide Residue in DNA	Molecular class
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T	thymine	deoxythymidine	pyrimidine

Term	Explanation
1691G>A	G-to-A substitution at nucleotide 1691
977insA	A inserted at nucleotide 977



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- Essential Ethics for Medical Communicators (ES) [2006], Cindy Hamilton
- Business Aspects of a Freelance Career (B/FL) [2500], Cindy Hamilton
- Summarizing Clinical Efficacy Data for a New Drug Application (RR) [4013], Peggy Boe
- Reporting Randomized Trials in Science Journals (ADV) [719], Tom Lang

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# Incredible Mentoring Program Within an Academic Center

By Haripriya Shankar, PhD

Having a great mentor can shape one's career, make it more fulfilling and enriching, and really propel it to the heights of success. There are different types of mentoring programs: formal, situational, and peer, to name a few.<sup>1</sup> In the December issue of the AMWA journal, Mary K. Dornhoffer describes a highly successful mentoring program at the Office of Grants and Scientific Publications (OGSP) at the University of Arkansas Medical Sciences (UAMS), which has provided scientific writing/editing assistance to numerous researchers and clinicians for nearly 20 years.<sup>2</sup> The OSGP offers a range of editing services including substantive editing; developing strategies for organizing text and graphics to communicate the information with clarity; editing for style, content, and grammar; and formatting text and figures.<sup>3</sup>

According to Mary K. Dornhoffer, "One of our goals as editors is to develop a good investigator/editor relationship that will facilitate mentoring on our part and trust on the investigator's part." The editing process at the OGSP is initiated with an informal face-to-face meeting between the investigator/s and the editor to ensure that the editor clearly understands the nuts and bolts of the project. This will help them communicate the underlying thought and the nuances in a simple yet an effective manner, while reducing the use of complex technical language. This is critical because academic writing can often be too jargon-laden. The use of specific jargon in an article is recommended only while writing for a specific group and should be avoided if it is targeted toward a broader audience.<sup>4</sup> The other goal of this meeting is to understand whether the investigator hopes to prepare a manuscript for peer-review or a grant for submission and to accordingly determine a timeline to accomplish these goals. After the initial meeting, an iterative editing process follows between the editor and the investigator to ensure that the final product (either a manuscript or grant proposal) is of the highest quality.

This type of a mentored-editing process is most useful for young investigators who have less experience in scientific writing, especially grant writing. This is also beneficial to the more seasoned investigators, especially in the current

climate of recurrent NIH funding cuts and shorter grant applications, where everyone is forced to write as concisely and creatively as possible to 'sell' their idea.

In addition to the one-on-one interactive session during the editing process, the OGSP conducts formal interactive workshops to train graduate students, postdoctoral scientists, residents, and young investigators to write manuscripts and different types of grants more effectively, and provides lectures on manuscript preparation and the peer-review process that is specifically tailored to the medical residents. These efforts have resulted in more publications in peer-reviewed journals and an increase in the number of grants being funded.

This service provided by the OGSP is fee-based due to the substantial time and effort spent by the editor on each assignment, and therefore, may not be suitable for everyone. Second, it is difficult to track the success rates due to lack of communication during a manuscript peer-review/revision process or the grant review/renewal process. Despite these issues, the OGSP continues to provide a great mentoring experience to those at UAMS and hopes to expand its services by presenting its workshops at scientific meetings to benefit others who may need their expertise and guidance.

## References:

1. <http://research.wustl.edu/Resources/PERCSS/library/Pages/mentoringtypes.aspx>
2. Dornhoffer MK. Beyond Editing: An Experience in Mentoring Provided by an Academic Health Care Center's Office of Grants and Scientific Publications. AMWA Journal. 2012. 27(4)147-151 (<http://www.amwa.org/default/publications/journal/vol27.4/vol27no4.htm>)
3. [http://cancer.uams.edu/ogsp\\_services](http://cancer.uams.edu/ogsp_services)
4. <http://owl.english.purdue.edu/owl/resource/608/01/>



# Medical Writing Certification--An Update on AMWA's Work in Progress

**Join us for a webinar on Mar 06, 2013 at 12:00 PM PST.**

Please join us for a Webinar presentation by Tom Gegeny on AMWA's development of a Medical Writing Certification. **This webinar is free to members of the NorCal and SoCal AMWA chapters;** however, you will need to register (Name and e-mail address) sometime within 1 hour prior to the meeting to participate.

**Description:** AMWA has embarked on an exciting new venture—creating a certification examination for medical writers. A cornerstone of this effort was the successful design and distribution in 2012 of a survey of more than 1,000 medical writers to assess the knowledge, skills, and abilities (KSAs) considered important for competence in the profession. A blueprint for medical writing certification is being drawn based upon the results of this landmark survey, research on other certification models (established or in progress) of sister organizations, and consultation from certification process and policy experts. So, where are we in this process? What does it mean for professional medical writers? How can you become involved? Find out answers to these questions and a great deal more as Tom Gegeny, immediate past chair of AMWA's medical writing certification commission, provides an update on this major initiative.

**Presenter:**

Thomas Gegeny has more than 12 years of experience in medical writing and publications. He is a certified Editor in the Life Sciences (ELS) and a certified medical publication professional (CMPP). He holds a master's degree in biomedical sciences (neuroscience) from the University of Texas–Houston Health Science Center. Tom is currently a Senior Medical Writer and Account Portfolio Lead with UBC-Envision Group, a medical publication agency that serves the pharmaceutical industry. Prior to his current position with Envision, Tom worked in the nonprofit sector and the information services industry including his roles as Executive Director and Senior Editor at The Center for AIDS Information and Advocacy in Houston and as Publications Specialist with the Houston Academy of Medicine–Texas Medical Center Library. Tom is a fellow of AMWA and has been a member since 1998. He served as AMWA's national president from 2009 to 2010. Tom recently chaired AMWA's medical writing certification commission (2011–2012) and continues to serve as a commission member.

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## Hellelil and Hildebrand, the Meeting on the Turret Stairs



"The Meeting on the Turret Stairs (also known as Hellelil and Hildebrand)," 1864, watercolor and gouache on paper, 95.5 x 60.8 cm.

By Sir Frederic William Burton (1816-1900), Irish painter and third director of National Gallery, London.

Location: National Gallery of Ireland, Dublin.

"The Meeting on the Turret Stairs" was inspired by an old Danish ballad "The Legend of Hellelil and Hildebrand (later translated into English in 1855 by Whitley Stokes). This richly colored evocative painting with fine brushstrokes depicts the final embrace of ill-fated lovers, a Danish princess Hellelil and her bodyguard Hildebrand in the medieval stone tower. Hellelil's father disapproving of their love ordered his seven sons to kill Hildebrand who fought and killed six, but spared the seventh brother of Hellelil on her request. Hildebrand died of his wounds and Hellelil soon afterwards from grief.

The brief embrace of Hellelil and Hildebrand where seconds appear to extend into eternity is one of the most beloved romantic Irish painting and was voted as the most favorite by the Irish public in 2012 in RTE ONE poll.

## **Job Listing Synopsis – March 2013**

**Sr. Medical Writer**  
UC San Diego

**Sr. Medical Writer (Multiple Positions)**  
East Janover, NJ

**Medical Writer**  
Los Angeles Area Biotechnology Company

**Scientific Technical Writer/Editor**  
Carlsbad, CA

If you'd like to share any job leads with the group or if you would like to receive more comprehensive listings, please e-mail Irene, [employment-coordinator@amwa-pacsw.org](mailto:employment-coordinator@amwa-pacsw.org) with your information and I'll add it to the job listings! And don't forget to join AMWA PacSW LinkedIn page to find job leads as well.